

CLAIMS:

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1. A kit for the identification of a diabetic patient's genetic polymorphism pattern at IL-1A, IL-1B(-511), and IL-1RN associated with increased risk of sight-threatening retinopathy, said kit comprising:

(a) DNA sample collecting means, and

(b) means for determining a genetic polymorphism pattern for IL-1A(-889), IL-1B(-511), and IL-1RN.

2. A kit according to claim 1, wherein the means for determining genetic polymorphism pattern comprises at least one polymerase chain reaction (PCR) primer wherein the PCR primer is selected from:

5'AAG CTT GTT CTA CCA CCT GAA CTA GGC 3' (SEQ ID No:1);
5'GTA CCT TCC GAG TAT ACA TT 3' (SEQ ID NO:2);
5'TGG CAT TGA TCT GGT TCA TC 3' (SEQ ID NO:3);
5'GTT TAG GAA TCT TCC CAC TT 3' (SEQ ID NO:4);
5'CTCAGCAACACTCCTAT 3' (SEQ ID NO:5);
5'TCCTGGTCTGCAGGTAA 3' (SEQ ID No.6);
5'TGTTCTACCACCTGAACTAGGC 3' (SEQ ID NO:7);
5'TTACATATGAGCCTTCCATG 3' (SEQ ID No.8);
5'AAGCTTGTCTACCACCTGAACTAGGC 3' (SEQ ID No.9); and
5'TTACATATGAGCCTTCCATG 3' (SEQ ID No.10).

3. A kit according to claim 1 or 2, wherein the means for determining the genetic polymorphism pattern include restriction enzyme digestion with restriction enzymes *NcoI*, *AvaI*, and *Bsu36I*.

4. A method of predicting increased risk of sight-threatening diabetic retinopathy, comprising the steps of:

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- (a) identifying in isolated genomic DNA from a sample previously taken from a diabetic patient a genetic polymorphism pattern for the genes IL-1A, IL-1B and IL-1RN;
- (b) comparing the identified pattern to control patterns of known polymorphisms; and
- (c) identifying diabetic patients expressing a genetic polymorphism pattern associated with increased risk of sight-threatening diabetic retinopathy.

5. A method according to claim 4, wherein said step for identifying in the DNA a genetic polymorphism pattern for IL-1A, IL-1B and IL-1RN comprises amplification of target DNA sequences with a polymerase chain reaction (PCR) and at least one PCR primer, wherein the PCR primer is selected from the group consisting of:

5'AAG CTT GTT CTA CCA CCT GAA CTA GGC 3' (SEQ ID No.1);
5'GTA CCT TCC GAG TAT ACA TT 3' (SEQ ID NO:2);
5'TGG CAT TGA TCT GGT TCA TC 3' (SEQ ID NO:3);
5'GTT TAG GAA TCT TCC CAC TT 3' (SEQ ID NO:4);
5'CTCAGCAACACTCCTAT 3' (SEQ ID NO:5);
5'TCCTGGTCTGCAGGTAA 3' (SEQ ID NO:6);
5'TGTTCTACCACCTGAACTAGGC 3' (SEQ ID NO:7);
5'TTACATATGAGCCTTCCATG 3' (SEQ ID NO:8);
5'AAGCTTGTCTACCACCTGAACTAGGC 3' (SEQ:ID NO:9); and
5'TTACATATGAGCCTTCCATG 3' (SEQ ID No.10).

6. A method according to claim 4 or 5, wherein said step for identifying in the DNA a genetic polymorphism pattern for genes IL-1A, IL-1B and IL-1RN comprises restriction enzyme digestion with restriction enzymes *NcoI*, *AvaI*, and *Bsu36I*.

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7. A method according to any of claims 4 to 6, wherein the DNA genetic polymorphism pattern associated with increased risk of clinically-significant macular edema comprises the presence at the combined loci of IL-1A plus IL-1B of at least three copies of the rarer allele for each loci (allele 2) between the two loci.

8. A method according to any of claims 4 to 7, wherein the DNA genetic polymorphism pattern associated with decreased risk of proliferative diabetic retinopathy comprises the presence of the genotype IL-1RN 2,2.

9. A method for predicting risk of sight-threatening diabetic retinopathy, comprising the steps of:

- identifying in isolated genomic DNA from a sample previously obtained from a diabetic patient a genetic polymorphism pattern for genes IL-1A, IL-1B and IL-1RN;
- identifying in the DNA a genetic polymorphism pattern for other genes associated with sight-threatening diabetic retinopathy;
- determining the number of polymorphisms carried by the diabetic patient that are associated with sight-threatening diabetic retinopathy risk, and identifying diabetic patients expressing a multiple genetic polymorphism pattern associated with risk of sight-threatening diabetic retinopathy.

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